

Dr. Albert Zickmann

SEP 28 2001

*510(K) Summary**General Information*

Classification Name:	Endosseous Implant
Common Name:	Prosthetic Dental Implant System
Trade Name:	Blue Sky Bio Dental Implant System
Submitter's Name:	Dr. Albert Zickmann
Address:	5455 N Sheridan Road, #3608 Chicago, IL 60640
Telephone:	773-769 2622
Fax:	978-246 2662
Contact:	Dr. Albert Zickmann
Date of Summary	January 2001

Device Description

The Blue Sky Bio Dental Implant System consists of root form dental implants of various lengths and diameters and associated abutment systems, which provide the clinician with cement retained and overdenture-type restorative options. Included in the system are drills, depth gauges, abutment drivers and wrenches. The implants and components are supplied sterile or not sterile and are labeled accordingly. The non-submerged portion of the implants is machined smooth and the submerged portion is blasted with resorbable particles.

The system is suitable for a one-stage protocol eliminating the need for a second uncover surgery. The Implant system is not intended for immediate loading.

The device is compatible with implants and components of ITI's one stage dental implant system and Lifecore's Stage-I dental implant system.

Intended Use

The Blue Sky Bio Dental Implant System is intended for use in either partially or fully edentulous mandibles and maxillae to give support to single or multiple units fixed dental prosthesis. It is also intended to give support to overdentures by means of o-ring abutments or bar-attachments.

Characteristic Comparison Chart

Feature	Subject Device	Predicate Devices	
	Blue Sky Bio Dental Implant System	ITI Solid screw implant K894593, K894595, K971578 and K920768	Paragon Screw-Vent System K950578 and K861426
Material	CP Titanium Grade 4, Ti-6Al-4V	CP Titanium Grade 4	Ti-6Al-4V
One Stage	Yes	Yes	NO
Coating	Blasted with resorbable medium	TPS	Blasted with resorbable medium, HA
Body Diameter (mm)	3.3, 4.1, 4.8	3.3, 4.1, 4.8	3.7, 4.7, 6.0
Collar Diameter (mm)	4.8, 6.5	4.8, 6.5	3.7, 4.7, 6.0
Collar Height (mm)	1.8, 2.8	1.8, 2.8	1.0
Lengths (mm)	8, 10, 12, 14	8, 10, 12, 14, 16	8, 10, 13, 16
External Screw Threads	Yes	Yes	Yes
Antirrotational feature	Internal Taper 8°	Internal Taper 8°	Internal Hex
Gamma Sterilized	Yes	Yes	Yes
Solid Abutment for Cemented Restoration	Yes	Yes	Yes
O-ring Abutment for partial or full overdenture	Yes	Yes	Yes
Instruments (surgical and restorative)	Yes	Yes	Yes
Intended Use	Implantation into the fully or edentulous ridge for support of single or multiple unit prosthesis	Implantation into the fully or edentulous ridge for support of single or multiple unit prosthesis	Implantation into the fully or edentulous ridge for support of single or multiple unit prosthesis

Predicate Devices

The data submitted in this 510(K) is in support of substantial equivalence of Blue Sky Bio Dental Implant System to ITI-Straumann's implant system (K894593, K894595, K971578 and K920768) and Paragon's Screw-Vent system (K950578, K861426). The Blue Sky Bio Dental Implant System is compatible with ITI's One-Stage implants and components as well as Lifecore's Stage-1 dental implant system and does not raise new questions of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 28 2001

Mr. Albert Zickmann
Doctor Albert Zickmann
5455 N. Sheridan Road #3608
Chicago, Illinois 60640

Re: K010882
Trade/Device Name: Blue Sky Bio Dental Implant System
Regulation Number: 872.3640
Regulatory Class: III
Product Code: DZE
Dated: March 15, 2001
Received: March 23, 2001

Dear Mr. Zickmann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

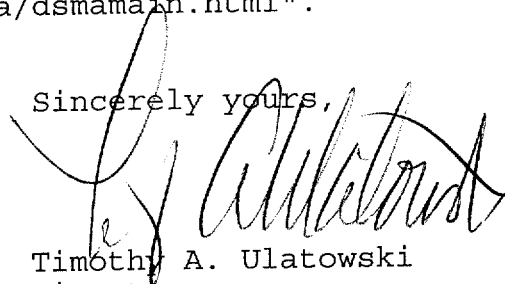
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Dr. Albert Zickmann

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Indications for Use Statement

Page 1 of 1

510(k) Number (if Known): K010882

Device Name: Blue Sky Bio Dental Implant System

Indications for Use:

- For Implantation into any area of the fully edentulous maxilla and mandible for the support of a removable or fixed dental prosthesis
- For Implantation into any area of the partially edentulous maxilla and mandible for the support of a removable or fixed dental prosthesis
- For single tooth or multiple unit prosthesis

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

Dr. Zickmann 510(k)

Susan Purper
(Division Sign-Off) Page 11
Proprietary & Confidential,
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010882

March 15, 2001